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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,627	12/12/2001	Heiner Max	100718- 357/Beiersdorf 75	9248

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,627

Applicant(s)

MAX ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, drawn to a method of preventing damage to DNA intrinsic to skin and/or for repairing existing damage to DNA intrinsic to skin, comprising topical administration of an effective amount of folic acid or derivatives thereof, classified in class 514, subclass 249.
 - II. Claims 5-8, drawn to a cosmetic preparation comprising an effective amount of dihydrofolic acid and/or tetrahydrofolic acid, classified in class 424, subclass 59.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method as claimed (i.e. repairing DNA damages in skin) could be practiced by materially different products, see US 5352458 (abstract, DNA repair enzyme containing liposomes) or US 6146616 (column 16, protecting agents (lupine oil and wheat germ) for DNA against damage). The composition as claimed can be used in a materially different process as well, for instance, see US 6011040 (tetrahydrofolic acid containing pharmaceutical composition for cardiovascular diseases).

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Additionally, the search of entire groups in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. Briscoe, Kurt on September 20, 2002 a provisional election was made with traverse to prosecute the invention of II, claims 5-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Status of Application

In response to the restriction requirement, applicant elected the group II, claims 5-8 with traverse. Non-elected claims 1-4 are withdrawn from consideration and the claims 5-8 are presented for the prosecution the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority, Germany10062401.4 filed on 12/14/2000 under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers including certified copy submitted, which papers have been placed of record in the file.

Information Disclosure Statement

1. Acknowledgement is made of Applicant's Informational Disclosure Statement(IDS) filed on 06/11/2002. IDS includes 7 foreign patented references among 11 references found to be non-english translated references. Even though the relevance of those references are states in separate sheet, the references without the english translation have not been considered at this time because the relevance of those said references could not been verified. Applicant is respectfully suggested to submit english translated copy of those said references. The references considered are initialed at the left column of the form PTO-1449. Pease refer to Applicant's copy of the form PTO-1449 submitted herewith.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT.

(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A
COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer
program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)),
and tables having more than 50 pages of text are permitted to be
submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A

“Sequence Listing” is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required “Sequence Listing” is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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2. Claims 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Barclay(US 2002/0035087A1).

Barclay teaches a cosmetic composition(see paragraph [0059-0060] at page 6) comprising dihydrofolic acid, tetrahydrofolic acid, 5-methyl tetrahydro acid, etc, see claims 53, 62 and 66.

As to composition claims 5-8 regarding the recited limitations(i.e. concentration of the dihydrofolic acid or tetrahydrofolic acid), Barclay teaches the effective concentration of folates used in his topical preparation, about 0.002mg/ml-10mg/ml(weight-volume), preferably 0.02-10mg/ml (see page 6, paragraph [0067]) which converts to weight percent, that is about 0.0002-1 weight percent(wt-%), respectively. All the critical elements required by the claims 2-8 are embraced by Barclay's teaching. Thus all the claims are anticipated.

Conclusion

3. No claim is allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or

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relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,

Patent examiner

September 20, 2002

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